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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,346	07/24/2001	Jian Ni	PF199D2	4955
22195	7590	02/04/2004	EXAMINER	
HUMAN GENOME SCIENCES INC 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER

1646

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/911,346

Applicant(s)

NI ET AL.

Examiner

Prema M Mertz

Art Unit

1646

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 21-28, 53-60, 95, 96, 126 and 127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 29-31, 34-52, 60-62, 65-83, 92-94, 97-115, 124 and 125 is/are rejected.
- 7) ☒ Claim(s) 32-33, 63-64, 95-96, 126-127 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1646

### DETAILED ACTION

1. Claims 21-28, 53-60, 84-91, 95-96, 116-123, 126-127, have been withdrawn from consideration. Claims 1-20, 29-52, 61-83, 92-94, 97-115, 124-127 and amended claim 92 (11/24/03) are under consideration.
2. Receipt of applicant's arguments and amendments filed on 11/24/2003 is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 11/24/2003:
  - (i) the rejection of claim 92 under 35 U.S.C. § 112, second paragraph.
4. Applicant's arguments filed <sup>on 11/24/2003</sup> ~~in Paper No. 84719/03~~ have been fully considered but were non-persuasive in part. The issues remaining ~~and new issues~~ are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 102***

6. Claims 1-2, 4, 8, 9, 10, 12, 16, 17, 29-31, 34, 36, 40-42, 44, 48-49, 61-62, 65-66, 68, 72-74, 79-80, 92-93, 94, 97, 99, 103-105, 107, 111-112, 124-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Shau et al. (US Pat No. 5, 250,295) in light of Shau et al. (US Pat No. 5, 610,286).

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action (8/27/03).

Applicants argue that the NKEF protein disclosed in reference and the NKEF C protein disclosed in the instant invention are distinct proteins. Furthermore Applicants argue that a comparison of NKEF A (SEQ ID NO:2 of the '286 patent) and the NKEF C of the

Art Unit: 1646

instant application in Figures 2A-2D show small portions of alignment. However, contrary to Applicants arguments, the instant protein has 68.8% identity with the protein of the reference. Applicants are reminded that it is well known in the art that only a stretch of 6 amino acids is required for eliciting an antibody response. (Harlow et al. 1988). There are several 6 amino acid stretches in common between the protein of the reference and the instant protein both of which belong to the same family of proteins. The essential disagreement appears to be the interpretation of what constitutes a “specifically binds” and since Applicants have not provided a definition for “specific” in the instant specification (see page 21), the antibody to the protein of the reference encompasses the antibody claimed.

Applicants argue that the NKEF polypeptides isolated in the ‘295 and ‘286 patents are not the NKEF C polypeptide of the instant invention. However, contrary to Applicants arguments, the Examiner is acknowledging that the protein of the prior art and the instant protein are not identical. However, since the reference anticipates the claims because more than half of the amino acids between the reference and instant protein are identical, it would be difficult to make an antibody to the polypeptide of the reference that would not bind to the instant polypeptide as set forth in SEQ ID NO:2. Therefore, it would be difficult for one of ordinary skill in the art to make an antibody to the protein of the prior art reference, which did not infringe on the antibody limitations of the instant claims.

***Claim Rejections - 35 USC § 103***

7a. Claims 3, 11, 35, 43, 67, 75, 85, 98, 106, 117 are rejected under 35 U.S.C. 103 as being unpatentable over Shau et al (U.S. Pat No. 5,250,295) in view of Lerner (1982), and Harlow et al. (1988).

Art Unit: 1646

This rejection is maintained for reasons of record set forth at pages 4-5 of the previous Office action (8/27/03).

Applicants argue that neither the combination of Shau, Lerner and Harlow nor the references individually disclose all the limitations of the present invention. However, contrary to Applicants arguments, if the references taught the monoclonal antibodies claimed in the instant application, this rejection would be a 35 U.S.C. 102 rejection rather than a 35 U.S.C. 103 rejection. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to use the amino acid sequences taught by Shau et al., to produce monoclonal antibodies with a predetermined specificity as taught by Lerner with the expectation that the large quantities of monoclonal antibodies made against the NKEC proteins would be useful in determining the location of the NKEF protein within the cell or to be used in animal model immunotherapy.

7b. Claims 5-7, 13-15, 37-39, 45-47, 69-71, 76-78, 87-89, 100-102, 108-110, 119-125 are rejected under 35 U.S.C. 103 as being unpatentable over Shau et al (U.S. Pat No. 5,250,295) in view of Queen et al. (U.S. Pat No. 5,953,101).

This rejection is maintained for reasons of record set forth at pages 5-6 of the previous Office action (8/27/03).

Applicants argue that neither the combination of Shau and Queen nor the references individually disclose all the limitations of the present invention. However, contrary to Applicants arguments, if the references taught the single chain and chimeric antibodies to the NKEC protein claimed in the instant application, this rejection would be a 35 U.S.C. 102 rejection rather than a 35 U.S.C. 103 rejection. Therefore, it would have been prima facie

Art Unit: 1646

obvious to one having ordinary skill in the art at the time the invention was made to use the amino acid sequences taught by Shau et al., to produce antibody fragments, and single chain and chimeric antibodies to the NKEC protein as taught by Queen et al.

7c. Claims 18-20, 50-52, 81-83, 100-102, 113-115, are rejected under 35 U.S.C. j 103 as being unpatentable over Shau et al (U.S. Pat No. 5,250,295) in view of Lerner (1982) and Harlow et al. (1988) as applied to claims 3, 11, 35, 43, 67, 75, 85, 98, 106, 117 above, and further in view of Sevier et al. (1981).

This rejection is maintained for reasons of record set forth at page 6 of the previous Office action (8/27/03).

Applicants argue that neither the combination of Shau, Lerner, Harlow and Sevier nor the references individually disclose all the limitations of the present invention. However, contrary to Applicants arguments, if the references taught the production of monoclonal antibodies using hybridomas, the monoclonal antibodies directed against the NKEC protein claimed in the instant application, this rejection would be a 35 U.S.C. 102 rejection rather than a 35 U.S.C. 103 rejection. Therefore, it would have been prima facie obvious at the time the invention was made to make the antigen as taught by Shau et al., and make antibodies as taught by Lerner, and Harlow et al., and it would also be prima facie obvious to make hybridomas to produce monoclonals as taught by Sevier et al., because Sevier et al. teach that the advantages of using monoclonal antibodies include homogeneity, specificity and are more easily available than polyclonal antibodies and because the use of hybridomas (cell lines generating monoclonal antibodies) provides a easily replenishable source of a highly selective antibody.

***Conclusion***

Art Unit: 1646

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

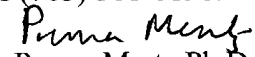
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Prema Mertz Ph.D.  
Primary Examiner

Application/Control Number: 09/911,346

Page 7

Art Unit: 1646

Art Unit 1646  
December 17, 2003